TABLE 21.—Continued

	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	TOTAL
Minimum age for sale or possession	18	18	18	18	16	16[a]	18	18	18	16	19	17	16	18	18			
Prohibits use or possession of tobacco by minors	X					X		X	X		X		X		X			16
Prohibits the sale of all tobacco products to minors	X	X		X			X	X		X	X	X	X	X	X			34
Prohibits the sale of cigarettes to minors	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			43
Prohibits the free distribution of tobacco to minors	X	X	X	X	X	X	X	X	X	X	X	X		X	X			41
Prohibits all free distribution of tobacco																		1
Prohibits cigarette vending machines accessible to minors											X							2
Requires signs posted at point of sale		X							X		X	X						11
Requires a license to sell tobacco	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	50
Provides for license revocation									X									4
Penalties	B	B	B	B	B	F	B	U	B	F	B	F	F	B	F			
Enforcement provisions			X[c e]				X[e]		X[f]						X[c]			7

TABLE 21.—Continued

NOTE: Since January 1, 1988, the following States have new age restrictions on the sale of tobacco products: CO, 18 years; CT, 18 years; GA, 17 years; HI, 18 years; NJ, 18 years; WI (effective 1989), 18 years.

[a]Applies only to cigarettes.

[b]F, fine; B, both jail or fine; U, unspecified.

[c]Provisions to encourage minors to divulge source of tobacco.

[d]For cigarettes only; minimum age for smokeless tobacco sale is 17 years.

[e]Provides a bounty to informers.

[f]Provides that it is not entrapment to send a minor into a store.

SOURCE: DiFranza et al. (1987); US DHHS (1986e).

covering not only tobacco sales, but also the use or possession of some form of tobacco by minors (DiFranza et al. 1987).

The minimum age for the legal purchase of tobacco ranges from 15 to 19 years. Two-thirds of the laws require the purchaser to be 18 years or older. However, 7 States that prohibit the sale of tobacco to minors allow children of any age to purchase tobacco if they have a note from their parent or guardian. An age limit of 19 years or higher has the theoretical advantage of ensuring that most high school students cannot legally use tobacco products. This would automatically ban student smoking on school grounds, make it easier for schools to eliminate tobacco and support other school-based anti-smoking efforts (Chapter 6).

The enforcement of tobacco access laws is left to local law enforcement officials in most States. The exceptions are New Hampshire, where the Commissioner of Revenue Administration sets enforcement rules, and Massachusetts, where the Department of Public Health enforces the law requiring that signs be posted at point of sale. Violation of tobacco access laws is a misdemeanor or petty offense, punishable by fine, imprisonment, or both. Minors found guilty of possession of tobacco face a fine under most laws and either fine or imprisonment in 3 States.

A few States have special provisions to facilitate enforcement. In Oklahoma and South Carolina, a portion of any fine levied against a merchant found guilty of selling tobacco to a minor goes to the witness who informed authorities of the violation (DiFranza et al. 1987). Tennessee law specifies that it is not entrapment for law enforcement authorities to have minors purchase tobacco for the purpose of monitoring retailer compliance with the law. Five States (Florida, Iowa, Nebraska, Oklahoma, and West Virginia) require minors caught in possession of tobacco to identify the person or business that provided the tobacco. In Nebraska and West Virginia, a juvenile who furnishes the identity of the person who provided the tobacco will be free from further prosecution (US DHHS 1986e).

With the exception of Virginia, the 43 States prohibiting tobacco sales to children also ban the distribution of free cigarette samples to minors. Communities that have banned all free cigarette distribution have also effectively banned distribution to children; these are discussed in the advertising section (Part I). A ban on all free distribution of tobacco products has been endorsed by the Surgeon General, the American Medical Association, the American Academy of Family Physicians, the Department of Health and Human Services, and others. In addition, opinion polls demonstrate that such an action is supported by a majority of the public (Davis and Jason 1988; Chapter 4).

By their design and intent, vending machines do not require supervision and allow easy access to minors (DiFranza et al. 1987). Despite survey data cited above suggesting that vending machines are an important source of cigarettes for children, as of October 1988, laws in only five States restrict minors' access to vending machines (Tobacco-Free America Project 1988b). Utah, Idaho, Alaska, and New Hampshire specify that vending machines must be inaccessible to minors, whereas Maine requires that vending machines be supervised by an adult (Tobacco-Free America Project 1988b). Nine States require the owners, operators, or supervisors of tobacco vending machines to post signs stating that minors are prohibited from purchasing cigarettes from that

machine (Tobacco-Free America Project 1988b). At least one locality has enacted a law requiring supervision of cigarette vending machines. King County, WA, will ban unsupervised vending machines in unincorporated areas as of February 1, 1989 (Coughlin 1988).

The World Health Organization, American Medical Association, American Cancer Society, American Heart Association, American Lung Association, and others have called for a ban on cigarette vending machines, citing them as a major obstacle to the enforcement of tobacco access laws (WHO 1975, 1976, 1985; Bennett 1985; AMA 1987; DiFranza et al. 1987). The analogy between alcohol and tobacco has been made: it is illegal to sell alcohol from vending machines, and the same standard could apply to tobacco (US DHHS 1988, Preface). According to Census Bureau data, in 1982, vending machine sales of cigarettes represented only 6.2 percent of all cigarette sales (US DHHS 1987e), suggesting that the absence of vending machines would result in little inconvenience to adult smokers.

In addition to laws restricting tobacco sales to minors, every State except West Virginia requires that an individual obtain a license before distributing, retailing, wholesaling, or manufacturing cigarettes and other tobacco products. This licensing requirement appears to be for the purpose of facilitating the collection of State excise taxes rather than for enforcing compliance with laws on tobacco sales. Only four States (Hawaii, Nebraska, Nevada, and Tennessee) permit a vendor's license to be revoked for selling cigarettes to minors (DiFranza et al. 1987).

Few community ordinances have addressed the sale of tobacco to minors, but in the past decade at least 14 local communities have banned the free distribution of tobacco products, generally for the purpose of limiting minors' access to tobacco (Davis and Jason 1988; Tobacco-Free America Project 1988b).

Compliance With Tobacco Access Laws

For a law to reduce or eliminate the commercial availability of tobacco products to minors, tobacco vendors must be aware of and comply with the law, and appropriate public officials must enforce it. Compliance with tobacco access laws has been evaluated by determining the degree of difficulty a minor has in obtaining tobacco products. Two methods have been used. The first is to ask children how difficult it is for them to obtain tobacco. In 1987, nearly 90 percent of a sample of Minnesota 10th grade students who smoked regularly reported that it would be very easy for them to obtain cigarettes, despite a State law banning cigarette sales to children under 18 years of age (Forster, Klepp, Jeffery, in press). A survey in New Jersey found that 90 percent of 508 current and former high school student smokers were always or nearly always able to buy tobacco products before age 16 (Slade et al., unpublished manuscript).

A second, more reliable method of assessing compliance is to observe directly the degree of compliance by individual merchants in an experimental situation. In a recent study, an 11-year-old girl was successful in 75 of 100 attempts to purchase cigarettes in Massachusetts, a State that prohibits the sale of cigarettes to children under 18 years of age (DiFranza et al. 1987). Compliance with the law was six times greater in stores where signs were posted compared with stores without signs. Similar data collected by

two nonprofit organizations, STAT (Stop Teen-age Addiction to Tobacco) and DOC (Doctors Ought to Care), and other investigators suggest that compliance with access laws is low throughout the United States (Kirn 1987; Altman et al. 1989; Slade et al., unpublished manuscript). Using the same method of sending a child into a business establishment to test compliance with the law, they found that an average of 80 percent of the retailers in five States were violating the law (Kirn 1987).

Two reasons have been identified for the failure of these laws to reduce children's access to tobacco: vendors are unaware of the laws, and State and local authorities fail to enforce the laws (DiFranza et al. 1987). Current laws provide no mechanism to inform tobacco vendors of their responsibility to prevent children from purchasing tobacco. As a result, many vendors are unaware that it is illegal to sell tobacco to minors. For example, in Massachusetts, one-third of tobacco vendors were unaware of the law (DiFranza et al. 1987), and in New York, 40 percent were uninformed (Cummings and Marshall 1988).

Knowledge of the law by tobacco vendors is necessary but not sufficient for the law to succeed; knowledgeable vendors must also comply with the law. In Massachusetts, 73 percent of vendors who knew that it was illegal to sell tobacco to minors sold cigarettes to an 11-year-old girl (DiFranza et al. 1987). This suggests that vendors either have little fear that noncompliance will be detected or are not deterred by the potential punishment. Retailers have a strong financial incentive to sell cigarettes to children. Although the size of the market is not known, one rough estimate is that cigarette sales to children under 18 years of age are worth nearly 500 million dollars per year, and smokeless tobacco sales to this age group are worth an additional 130 million dollars (Slade 1988a). As noted above, it appears that children purchase most of their cigarettes themselves. Compliance will be achieved only if retailers are not only aware of tobacco access laws but also deterred from violating them by adequate penalties and effective enforcement. It has been estimated that there are hundreds of millions of such violations annually, yet law enforcement officials throughout the country have difficulty recalling instances in which a vendor was charged with violating the law (Kirn 1987). Under these circumstances, tobacco vendors may have little fear of prosecution, and therefore, little incentive to comply with the law. They may also not appreciate the magnitude of harm caused by tobacco or the importance of their sales in the initiation of smoking.

There are several reasons why these laws are not enforced. The provisions of some laws make enforcement difficult. In Washington, DC, for example, an arrest cannot be made without a warrant, and the arresting officer must personally witness the crime. Indiana law provides that a vendor may use as a defense that he or she "reasonably believed that the buyer or taker was at least eighteen years of age." This places the burden on the prosecutor to prove not only that a child under 18 was sold tobacco, but also that the child would appear under age to a reasonable person.

A 1987 survey of law enforcement officials in 25 States identified attitudinal barriers to the enforcement of tobacco access laws (Uzych, unpublished manuscript). Overall, the officials felt that the laws could not, should not, or need not be vigorously enforced. The most commonly held belief was that the laws were unenforceable. There was substantial evidence that little or no effort was being made to enforce tobacco access laws.

The most common policy cited by survey respondents was to enforce the law "only if specific complaints have been received," or "only if violations are conspicuous." Some respondents felt the law was self-enforcing for retailers, while others felt enforcement of tobacco access laws was not the business of law enforcement officials, because tobacco sales to minors is a "health issue rather than a public safety issue"; "tobacco, a legal substance, does not have as a side effect anti-social behavior"; or "possession of tobacco by a minor is not . . . considered a grave offense" (Uzych, unpublished manuscript). These data suggest that widespread and substantial changes in the attitudes and priorities of law enforcement officials would be needed if conventional enforcement were to become effective. These changes include a shift in attitudes about the importance of smoking by children, the importance of enforcement, and the ability of law enforcement officers to enforce the law.

An alternative approach to enforcement that has been suggested is to transfer the responsibility from law enforcement agencies to public health departments (DiFranza, 1988). Public health departments traditionally have had both enforcement and licensing responsibilities. Public health inspectors routinely make unannounced visits to restaurants and food stores to monitor compliance with health and safety statutes. They are given the authority to issue citations or to revoke a vendor's license. Public health inspectors could also be assigned to ensure that tobacco vendors comply with tobacco access laws. It has been suggested that revenues from fines and the licensing of vendors might cover the cost of enforcement and even potentially be a source of State revenues (DiFranza 1988). It has also been suggested that some of the estimated excise tax revenues derived from the sale of tobacco to children be dedicated to enforcement. For New Jersey alone, this was recently estimated at 3 million dollars per year (Slade 1988a).

As an alternative to increasing enforcement, efforts could be made to increase tobacco vendors' knowledge of and compliance with existing laws. Educational efforts that target tobacco vendors have recently been developed in several States. They have shown promise in preliminary studies (Altman et al. 1989; Slade et al., unpublished manuscript). One study in Santa Clara County, CA, documented a significant reduction in illegal tobacco sales to minors after a 6-month campaign using mass media, direct merchant education, contact with management of chain stores and franchises, and community organization (Altman et al. 1989).

Legal tactics to increase compliance have also been pursued, so far without success. In *Parker* v. *City School Superintendent*, action was brought against school officials for providing students with a smoking lounge in a State that prohibited smoking by children under 18 (Jacobs 1974). The Supreme Court of Missouri ruled that smoking of cigarettes by minors was a misdemeanor and did not give rise to a civil cause of action. In another case, the Group Against Smoking Pollution (GASP) of Massachusetts filed a lawsuit on behalf of a 16-year-old girl who began smoking at the age of 14 and was illegally sold cigarettes for 2 years by a local convenience store. The suit charged the convenience store chain and the cigarette manufacturer with the "negligent entrustment of a dangerous instrumentality to minors" in violation of a State law prohibiting the sale of tobacco to minors. The case is pending (GASP 1987).

Effects of Current Access Laws

There has been little systematic evaluation of the impact of tobacco access restrictions. As described above, considerable evidence indicates that compliance is low and enforcement is poor, with the result that tobacco products are relatively easy for children to obtain. Under these circumstances, it is impossible to test hypotheses about the impact of tobacco access restrictions on smoking behavior.

It would be surprising if laws as currently implemented had much effect on the initiation of tobacco use by children. If tobacco access laws were adequately implemented, it would be possible to test the effect of a program of merchant education or strong enforcement on tobacco availability and, ultimately, on smoking behavior. However, comparisons of adolescent smoking rates in States with and without tobacco access laws or strong enforcement might be confounded by other cultural, economic, and demographic factors that can affect the prevalence of smoking among children.

Summary

Despite existing legislation in 43 States and the District of Columbia restricting the sale of cigarettes to minors, tobacco products are relatively easy for children to obtain. Tobacco vendors are often unaware of tobacco access laws, and law enforcement agencies do not enforce them. Furthermore, there are gaps in legislation. Seven States currently have no law prohibiting the sale or distribution of cigarettes to minors, and laws in many other States are not comprehensive. For example, some laws do not include all tobacco products, and a dozen permit children under 18 years of age to be sold tobacco. Only a few prohibit the use or possession of tobacco by children.

This situation could be ameliorated by improving the compliance with and enforcement of laws currently in effect, by amending current legislation, and by enacting new legislation. Because even new legislation would require adequate implementation to achieve its goals, efforts to ensure compliance with and enforcement of tobacco access laws are essential to achieve meaningful reductions in the availability of cigarettes to children. Moreover, interest in the enactment of new laws might be limited by the poor compliance record of past legislation, suggesting the importance of improving the implementation of existing laws.

The adoption of a uniform comprehensive tobacco access law throughout the United States has been proposed by several groups as one means to eliminate some of the loopholes through which children now legally obtain and use tobacco (AMA 1987; DiFranza et al. 1987; Stanwick et al. 1987; Cummings and Marshall 1988). The sale of tobacco to minors has been banned on a national level in Great Britain and Canada (Walker 1980; Stanwick et al. 1987). Model tobacco access laws, designed to protect children from tobacco, have been developed by the American Medical Association (AMA) and others (AMA 1987; DiFranza et al. 1987; Stanwick et al. 1987; Cummings and Marshall 1988). The provisions of these laws are similar. A number of provisions are borrowed from alcohol control efforts; these include banning all sales to minors, limiting sales to a small number of licensed vendors (which would eliminate vending machine sales), and requiring purchasers to show positive proof of age. Legislation

was introduced in the 100th Congress (H.R. 3658) that would prohibit the sale of cigarettes and other tobacco products to anyone under the age of 18, limit sales to over-the-counter sales (that is, prohibit vending machine sales), and require every retail establishment selling tobacco products to post conspicuously a sign stating, "The Sale of Cigarettes to Minors is Strictly Prohibited" (Atkins 1987). Proponents of comprehensive access laws draw an analogy between alcohol and tobacco and express the view that the sale of tobacco should be considered as seriously as the sale of alcohol and other addictive drugs (US DHHS 1988, Preface; Stanwick et al. 1987).

Federal Regulation of Tobacco Products

Because the use of tobacco products is hazardous to the health and safety of consumers, the regulation of tobacco products would be consistent with the established tradition of health and safety regulation for other consumer products. However, with few exceptions (e.g., see Part I regarding labeling and advertising regulations), none of the Federal agencies charged with health and safety regulation has taken regulatory action against tobacco products, due in part to specific statutory restrictions. There are a number of possible reasons for the lack of regulation, including the fact that millions of Americans became addicted to tobacco before its hazards were understood (Walsh and Gordon 1986).

In contrast to its approach to tobacco, Congress has passed a number of laws over the last two decades that strictly regulate other hazardous consumer, environmental, and occupational exposures. The primary aim of these laws is to reduce the risk of cancer, reproductive hazards, and injuries. An analysis by Morrall (1986) of the impact of 26 final rules promulgated under these acts suggested that the estimated number of lives they saved collectively each year was far smaller than the annual number of lives lost because of cigarette smoking. Doll and Peto (1981) have estimated that the proportions of cancers attributable to occupational and environmental exposures are 4 and 2 percent, respectively, in contrast to the estimated 30 percent of cancer deaths that are caused by smoking (Chapter 3).

This Section examines the history of tobacco product regulation for health and safety purposes. The focus is on actions of the Federal Government, although relevant State actions are also mentioned.

Regulation of Tobacco Products Prior to 1964

In 1892, during a period in which several States were considering bans on cigarette sales, the U.S. Senate's Committee on Epidemic Diseases studied the cigarette issue and decided it was properly a State matter (Dillow 1981). By 1908, 11 States had banned the sale of cigarettes, primarily on the basis of aesthetic and moral objections and on the basis of health concerns that were poorly documented at that time. The laws proved unenforceable and were gradually repealed (Dillow 1981; Whelan 1984).

The Food and Drugs Act of 1906, the first Federal food and drug law, contained no express reference to tobacco products. It defined a drug as including medicines and preparations recognized in the United States Pharmacopeia (USP) or the National For-

mulary. Tobacco was listed in the 1890 edition of the USP, but it was deleted in the next edition, which was released in 1905. Neuberger (1963) stated that this deletion was rumored to have been made in exchange for support from tobacco-State Congressmen for passage of the law.

The 1906 Act also defined a drug as including substances intended to be used for the cure, mitigation, or prevention of disease in man or other animals. In 1914, the chief of the Bureau of Chemistry in the U.S. Department of Agriculture, the predecessor to the Food and Drug Administration (FDA), interpreted the 1906 Act by advising:

> [T]obacco and its preparations, when labeled in such a manner as to indicate their use for the cure, mitigation, or prevention of disease, are drugs within the meaning of the act, and, as such, are subject to the provisions thereof.
>
> On the other hand, tobacco and its preparations which are not so labeled and are used for smoking or chewing or as snuff and not for medicinal purposes are not subject to the provisions of the act (USDA 1914).

The 1906 Act was superseded in 1938 by the Federal Food, Drug, and Cosmetic Act (FFDCA), which gives FDA jurisdiction with respect to food, drugs, medical devices, and cosmetics. The definition of drug was expanded to include articles recognized in the Homeopathic Pharmacopeia. The current Homeopathic Pharmacopeia contains a monograph (i.e., a listing) for tobacco in the form of a tincture for application as a drug. Conventional cigarettes made from tobacco leaves are not recognized as drugs in any of the official compendia referred to in the "drug" definition of the FFDCA.

As further revised, the definition of "drug" in the FFDCA also includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" (FFDCA).

The FFDCA has not referred specifically to tobacco products as articles either within or outside the scope of jurisdiction under the Act. Tobacco products, as they have been customarily marketed, have not been considered by the FDA to fall within any of the categories over which the agency has jurisdiction (Young 1988). However, the agency has taken jurisdiction over tobacco products on the grounds that they are "drugs" when the manufacturer or vendor has made medical claims for the product (Young 1988). The FDA used this authority to assert jurisdiction over cigarettes in two cases during the 1950s, in which the FDA's jurisdiction was upheld in court. The first action involved Fairfax Cigarettes, which the manufacturer claimed to prevent respiratory and other diseases (*United States* v. *46 Cartons . . . Fairfax Cigarettes* 1953). The second action involved Trim Reducing-Aid Cigarettes, which contained the additive tartaric acid, which was claimed to aid the smoker in weight reduction (*United States* v. *354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes* 1959).

In a 1952 court case that involved the Federal Trade Commission (FTC), the FTC contended that the manufacturer deceptively advertised Chesterfield cigarettes and that the cigarettes were a drug by a definition virtually identical to that in the FFDCA (*Federal Trade Commission* v. *Liggett and Myers Tobacco Company* 1952). The court ruled that Chesterfield cigarettes did not meet the definition of a drug at issue in the case. The FTC argument that the cigarettes were a drug was based in part on two types

of representations by the manufacturer. The first type was that the cigarettes did not cause irritation of the throat and nose. The court ruled that this was not an affirmative claim of a beneficial effect or therapeutic purpose, but was merely a representation that the cigarettes had a nonadverse effect, and that such a representation was insufficient to find the product to be a drug. The second type of representation, which the FTC relied upon in asserting that the cigarettes were intended by the manufacturer to affect the functions of the body, was that the cigarettes had a "soothing effect." This was considered by the court to be not the type of bodily effect contemplated by the statute.

The FDA received new authority to regulate consumer products in 1960, with passage of the first Federal Hazardous Substances Labeling Act (FHSA), under which the definition of hazardous substance comprised six categories including toxic, corrosive, irritant, strong sensitizer, flammable, or pressure-generating substance, which may cause substantial personal injury or illness during or as a result of customary or reasonable use. Tobacco products were not specifically excluded. However, the FDA did not regulate tobacco products under that law.

In 1963, FDA expressed its interpretation that tobacco did not qualify as a hazardous substance under the FHSA. It noted that tobacco did not appear to fit within any of the FHSA's six classifications, and that at no time during the congressional consideration of the FHSA was there any indication that it was intended to cover tobacco (FDA 1963). In the same document, FDA also noted that the Surgeon General of the Public Health Service had recently appointed an Advisory Committee on Smoking and Health, and FDA stated its preference to withhold making any recommendations on Federal action regarding tobacco until the committee's report was issued (FDA 1963).

Regulation of Tobacco Products After 1964

Following the 1964 Surgeon General's Report, Congress considered a number of bills to regulate tobacco. From 1965 through 1978, over 75 bills were introduced into Congress on a wide variety of issues designed to address the smoking problem (Klebe 1979). The first U.S. House of Representatives bill dealing with smoking (H.R. 2248, 89th Congress) proposed amending the FFDCA to place cigarettes under the authority of the FDA. Because there was no known safe level for tar, nicotine, or other tobacco constituents, regulation would have likely resulted in prohibition of a product that was widely used. Instead, following considerable debate, the House Committee on Interstate and Foreign Commerce reported out H.R. 3014 (89th Congress), which called for warning labels on packages. This bill, along with its Senate counterpart, led to the first Federal cigarette labeling act (see Part I).

Other bills to regulate tobacco products indirectly by encouraging or requiring lower tar or nicotine levels were introduced. Of the bills filed during the next 6 sessions, 13 contained provisions for taxing cigarettes according to tar and nicotine content or cigarette length. Three other bills would have established maximum levels for tar and nicotine content or cigarette length. None of these bills became law.

Consumer health and safety laws enacted after 1964 might have led to the regulation of tobacco products. However, tobacco was specifically excluded in virtually all major bills passed after 1964. In 1970, Congress passed the Controlled Substances Act to

prevent the abuse of drugs, narcotics, and other addictive substances. In view of the scientific knowledge of nicotine's effects subsequently reported in the 1988 Surgeon General's Report (US DHHS 1988), nicotine would seem to be the type of substance the statute was intended to regulate. However, the law specifically excluded tobacco from the definition of a "controlled substance" in 21 U.S.C. 802(6).

In 1972, Congress passed the Consumer Product Safety Act (CPSA) and established the Consumer Product Safety Commission (CPSC), an independent regulatory agency, to administer the law. The Act excluded tobacco and tobacco products from the definition of "consumer product" (15 U.S.C. 2052 (a)(1)(B)). The Act also transferred authority for FHSA from the FDA to CPSC. Tobacco had not been exempted from FHSA when it was first passed in 1960. The American Public Health Association and others petitioned CPSC to set a maximum level of 21 mg of tar in cigarettes, under the authority of FHSA. In 1974, CPSC voted 3 to 2 that it lacked the authority to do so. The decision was appealed, and in April 1975, the U.S. District Court for the District of Columbia ruled that CPSC had jurisdiction and ordered it to consider the petition (*American Public Health Association* v. *Consumer Product Safety Commission* 1975). On May 11, 1976, Congress amended FHSA to exclude tobacco or tobacco products from the definition of hazardous substances. After this action, the court's decision was moot (Klebe 1979). The Senate report on the action stated that the change was made to clarify Congress' original intent and "should not be interpreted as reflecting any new judgment on smoking and health" (Senate Report No. 94-251 (June 24, 1975) for Public Law 94-284).

In 1976, Congress passed the Toxic Substances Control Act. One purpose of the Act was to "regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment . . . " (15 U.S.C. 2601 (b)). Evidence reported in the Surgeon General's reports indicates that tobacco and tobacco products could have otherwise met the definition of "chemical substance" under the Act. However, the Act excluded tobacco and tobacco products from that definition (15 U.S.C. 2602(2)(B)(iii)).

In 1977, the FDA was petitioned by Action on Smoking and Health (ASH) and others to assert jurisdiction over cigarettes as a "drug" or a "medical device" under the definitions of the FFDCA and to restrict the sale of cigarettes to pharmacies. FDA denied those requests (FDA 1977, FDA 1980), finding that the administrative records relating to the requests did not contain the requisite evidence of intended use to bring cigarettes within the drug or device definitions. ASH appealed the 1977 denial of its request that FDA assert jurisdiction over cigarettes as a drug. The U.S. Court of Appeals for the District of Columbia Circuit upheld the FDA's interpretation of the scope of its jurisdiction over cigarettes (*Action on Smoking and Health* v. *Harris* 1980). ASH did not appeal FDA's denial (FDA 1980) of the request by ASH that FDA assert jurisdiction over cigarettes as medical devices.

In 1988, the Coalition on Smoking OR Health petitioned the FDA to declare low-tar and low-nicotine cigarettes to be a drug, asserting that manufacturers market them with the intent of creating a consumer perception that they will mitigate or prevent disease (Coalition on Smoking OR Health 1988a). The petitioners introduced evidence obtained through the discovery process in a 1988 New Jersey tobacco product liability lawsuit that, in their view, documents manufacturer intent. In that suit, the jury found

that the tobacco manufacturer had made express warranties to the consumer about the health aspects of its cigarettes (*Cipollone* v. *Liggett Group Inc. et al.* 1988). The petition was pending as of November 1988.

The issue of whether tobacco could be classified as a hazardous substance under FHSA was addressed again in 1984 in a tobacco product liability suit (*Palmer* v. *Liggett Group Inc.* 1984). The plaintiffs claimed that the tobacco manufacturer violated FHSA by failing to place warning labels on cigarette packages from 1960, when the first FHSA became law, until 1965, when the Federal Cigarette Labeling and Advertising Act preempted cigarette labeling except as required under the Cigarette Act. The U.S. District Court dismissed this claim, citing the legislative history of FHSA as evidence that the intent of the legislators was not to cover tobacco, but to protect against accidental poisonings by household chemicals.

In 1985, the Massachusetts Department of Public Health, acting under the authority of the State hazardous substance law, which was modeled after the Federal law, declared oral snuff to be a hazardous substance and required protective labeling on packages as of July 1985. The State law, unlike the Federal statute, was never amended to exclude tobacco. The Massachusetts action was followed by a wave of labeling bills in other States and, the following year, by Congress' passage of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Public Law 99-252). That Federal law preempted the Massachusetts labeling requirement. However, oral snuff is still classified as a hazardous substance in Massachusetts (Connolly et al. 1986).

Tobacco products have also been classified as hazardous substances in another State. In 1986, California adopted the Safe Drinking Water and Toxic Substances Enforcement Act, which requires warnings for and regulation of chemicals known to cause cancer and reproductive toxic effects (Kizer, Warriner, Book 1988). Tobacco has been identified as a carcinogen and reproductive toxicant under the law. In August 1988, four environmental groups announced plans to file a lawsuit that would require that a warning label about cancer and reproductive risks be placed on store shelves containing tobacco products that do not carry the Surgeon General's warning. These products include cigars, pipe tobacco, and roll-your-own cigarette tobacco (Matthews 1988). In a settlement reached on October 18, 1988, 25 tobacco manufacturers agreed to place a warning label on cigars and pipe tobacco sold in California (Wilson 1988a). Canada has also defined tobacco as a hazardous product in Federal legislation passed in 1988 (House of Commons of Canada 1988; C-204, 1988).

Currently, most Federal regulation of tobacco products is administered by the Bureau of Alcohol, Tobacco, and Firearms (BATF) of the Department of the Treasury, and by the Federal Trade Commission (FTC). Regulation by BATF involves tobacco taxation with no intended impact on public health concerns, while the FTC actions involve advertising of tobacco products and the disclosure of health risks, as described in detail in Part I of this Chapter.

Environmental Tobacco Smoke Exposure

The Occupational Safety and Health Act, passed in 1970, empowers the Labor Department's Occupational Safety and Health Administration (OSHA) to ensure that:

> Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

OSHA has set standards limiting occupational exposure to 24 airborne materials that are present in tobacco smoke, including carbon monoxide and acrolein. Even though environmental tobacco smoke (ETS) is not excluded from OSHA's review, the agency has not sought to regulate it. A 1986 petition (Horne et al. 1986) requested OSHA to classify ETS as a category I potential occupational carcinogen. The petition was denied. In 1987, ASH, joined by the American Public Health Association and the Public Citizens Health Research Group, requested an emergency temporary standard to prohibit smoking in indoor workplaces under the authority of the OSHA law. As of November 1988, these petitions were pending (Public Citizen 1987).

The Clean Air Act of 1963 (Clean Air Act 1963) requires the Environmental Protection Agency (EPA) to regulate airborne pollutants. EPA has set standards for maximum acceptable exposures to pollutants that are also constituents of ETS, including carbon monoxide and nitrogen dioxide. However, EPA has interpreted the statute to apply to outdoor air pollutants only and has not moved to regulate exposure to ETS.

Tobacco Product Additives

Exclusion of tobacco and tobacco products from Federal health and safety laws also resulted in the exemption of tobacco product additives from regulatory review. The 1981 Surgeon General's Report, *The Changing Cigarette*, noted that additives may be in greater use in the low-tar brands to compensate for a loss in "flavor" brought about by tar reduction (US DHHS 1981a). The Report noted that it was impossible to assess the risks of the additives because manufacturers were not required to disclose the additives. The issue of additives was raised again in the 1984 Surgeon General's Report, citing the presence of powdered cocoa, which had been shown to enhance the carcinogenicity of tar. The Report observed:

> A characterization of the chemical composition and adverse biological potential of these additives is urgently needed, but is currently impossible because cigarette companies are not required to reveal what additives they employ in the manufacture of cigarettes (US DHHS 1984).

A 1978 amendment to the Public Health Service Act (Public Law 95-626) contained a number of tobacco-specific provisions. One called for a Department of Health and Human Services (DHHS) study of the health risks of cigarette additives. Attempts by DHHS to obtain complete, updated lists of additives from tobacco manufacturers were unsuccessful (Cummins 1983). As discussed in Part I of this Chapter, the Comprehensive Smoking Education Act of 1984 (Public Law 98-474) required manufacturers to provide the Secretary of DHHS with a list of all ingredients. However, the Secretary's authorities were limited to conducting research on the additives and reporting back to Congress with findings on their potential health effects. No authority was granted to restrict or eliminate ingredients found to be harmful.

In 1988, CA. Blockers, Inc., announced development of a cigarette additive that allegedly blocks the action of nitrosamines and its carcinogenic metabolites contained in tobacco smoke. The company intended to introduce the product into the market without FDA approval, stating that the company would make no health claims (CA. Blockers, Inc. 1988). However, the company's prospectus describes the action of the additive as blocking receptors in the lungs and states that its goal is "to eliminate a health risk associated with cigarette smoking" (CA. Blockers, Inc. 1987). The FDA has initiated an investigation of this matter, which was under review as of November 1988.

Fire Safety of Cigarettes

Over 1,500 deaths each year are caused by fires ignited by burning cigarettes (Hall 1987). Even though this number is low in comparison with the estimate of 390,000 deaths caused by smoking-related diseases (Chapter 3), public concern is high because many victims are nonsmoking infants and children or disabled persons (Botkin 1988). Congressional legislation calling for "fire-safe" (e.g., self-extinguishing) cigarettes was first introduced in 1974 and reintroduced in 1979. In 1983, eight States considered similar legislation but none was enacted (McGuire 1983; Garner 1985). In 1984, Congress passed the Cigarette Safety Act (Public Law 98-567). The purpose of the law was to

> determine the technical and commercial feasibility of developing cigarettes and little cigars that would be less likely to ignite upholstered furniture and mattresses (CPSC 1987).

The Act established an Interagency Committee (IAC) for Cigarette and Little Cigar Fire Safety that included representatives from CPSC, DHHS, and the U.S. Fire Administrator's Office. The IAC was advised by a Technical Study Group (TSG), which was charged with undertaking "such studies and other activities as considered necessary and appropriate to determine the technical and commercial feasibility" of developing a fire-safe cigarette. Following 2 years of work, TSG concluded that it is technically feasible and may be commercially feasible to develop a cigarette with a significantly reduced potential for igniting fires. After reviewing these findings, IAC concluded that issues concerning the economic feasibility, consumer acceptance, and health implications were unresolved. IAC recommended the formation and funding of a new advisory committee that, within 2 years of its formation, would develop and test a prototype of a less ignition-prone cigarette. Two months before IAC made its report to Congress, a major cigarette manufacturer announced the development of a new product, commonly referred to in the press as a "smokeless cigarette" that, when lying flat, is purportedly unlikely to ignite most materials with which it comes into contact (R.J. Reynolds Tobacco Co. 1987) (see below). Legislation was introduced in the 100th Congress to fund work of the new advisory committee and also to require the FDA to set fire safety standards (H.R. 3440, S. 1763).

Smokeless Tobacco Products

When the 1964 Surgeon General's Report was issued, the use of snuff and chewing tobacco was on the decline and there was little interest in Congress or the public health community in dealing with smokeless tobacco. In 1965, the Federal excise tax on smokeless tobacco products was repealed. Smokeless tobacco products, particularly moist snuff, were more aggressively marketed in the late 1970s by tobacco manufacturers and promoted as an alternative to the cigarette (Connolly et al. 1986).

In the absence of restrictions on advertising, moist snuff was marketed without warning labels on television and in other media. From 1978 through 1985, sales for moist snuff rose by 55 percent. By 1985, there were an estimated 13 million users nationally, of whom 3 million were below 21 years of age (US DHHS 1986c). Tobacco manufacturers developed low-nicotine snuff products that may be used as a "starter" to snuff use. A graduation strategy was employed in which the new users were encouraged to switch to higher nicotine brands over time (Connolly 1986; Connolly et al. 1986; Feigelson 1983).

As described in Part I, legislation to require health warning labels on smokeless tobacco packages was pending in 26 States when manufacturers, faced with the possibility of multiple different State labeling requirements, sought a uniform national law that preempted State action (Connolly et al. 1986). One State (Utah) considered but did not pass legislation to ban smokeless tobacco use (Utah House of Representatives 1986). Existing policies for cigarettes (excise taxes, prohibition on sales to minors, ban on television advertising, and warning labels on packages and print ads) were extended to apply to smokeless tobacco at the Federal and State levels.

Alternative Nicotine-Containing Products

Beginning in 1985, tobacco manufacturers introduced a variety of new products that delivered nicotine to the user and produced little or no smoke. The public health impact of the marketing of these new products is unknown because limited information is available about the products or their appeal. The 1988 Surgeon General's Report on nicotine addiction compared the use of the alternative nicotine delivery systems, in combination with regular cigarettes, with the "nonmedically approved use of methadone by opioid-dependent individuals when their drug of choice (e.g., heroin) is not available, and they are not involved in treatment for opioid dependence" (US DHHS 1988). The public health community has expressed concern that the alternative nicotine delivery systems will encourage experimentation among non-tobacco-using adolescents, will be used as an alternative to cessation by current smokers, may encourage relapse among former smokers, and may be used where smoking is prohibited (Slade 1988b; AMA 1988; Coalition on Smoking OR Health 1988b). The 1988 Surgeon General's Report called for an evaluation of the potential toxic and addictive effects of new nicotine-containing products (US DHHS 1988).

Whether these alternative nicotine delivery products are "drugs" or "devices" as defined by the FFDCA (and therefore subject to FDA jurisdiction) is being addressed

on a case-by-case basis. The Commissioner of the FDA took the following position in testimony before Congress:

> [T]he Agency must attempt to differentiate between the traditional tobacco product marketed without medical claims, and therefore not regulated by FDA, and the newer innovations designed to deliver nicotine to satisfy a nicotine dependence or otherwise to affect the structure or function of the body. FDA must decide, on a case-by-case basis, which product is subject to the FDC Act (Young 1988).

The FDA has reviewed or is reviewing four nicotine-containing products described below. In three cases, the FDA exerted jurisdiction over the product; two of these were removed from the market and one was approved for sale as a new drug. A decision in the fourth case has not been reached, as of November 1988.

A device called the Favor Smokeless Cigarette was introduced in 1985. This cigarette-sized white plastic tube had a fibrous plug impregnated with nicotine at one end. Users sucked air through the other end, drawing a nicotine aerosol into the oral cavity. The product contained nicotine purportedly derived from tobacco but did not contain tobacco leaf. In February 1987, the FDA determined that Favor was "a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body" (FDA 1987a; Young 1988; FDA letter to Congressman Waxman 1987b). As such, it met the FDA definition of a drug. The FDA also determined that Favor was a "new drug" within the meaning of the FFDCA because its composition was not generally recognized as safe and effective under the prescribed or recommended conditions of use (Young 1988). The FDA went on to state in the regulatory letter (FDA 1987a):

> The medical literature clearly recognizes that nicotine is well absorbed from the lungs; that it has potent pharmacologic effects, including effects on the nervous system; and that nicotine is a drug of dependence. . . . [I]t is our position that Favor is a nicotine delivery system intended to satisfy a nicotine dependence and to affect the structure and one or more functions of the body. Because of its intended uses, Favor is a drug as defined within section 201(g) of the Federal Food, Drug, and Cosmetic Act.

In 1987, the Pinkerton Tobacco Company introduced Masterpiece Tobacs, a tobacco chewing gum containing approximately 1 mg of nicotine. By the appearance and function of the product, the FDA determined that it was a food and because it contained tobacco, which is generally not considered safe for use in foods, it was an adulterated food. Both products, Favor Smokeless Cigarettes and Masterpiece Tobacs, have been removed from the marketplace (FDA letter to Congressman Waxman 1987b). A tobacco toothpaste containing ground snuff was introduced for sale in Indian food stores in the United States in 1987. Possible regulation was under review by the FDA as of November 1988.

The FDA has approved and allowed for sale nicotine polacrilex chewing gum, intended and labeled as a smoking cessation product and available only with a physician's prescription. The manufacturer subjected the gum to new drug safety and efficacy testing as a smoking cessation aid, and a New Drug Application for the product was approved in January 1984 (FDA letter to Congressman Waxman 1987b; Chapter 6).

In the fall of 1987, R.J. Reynolds Tobacco Company (RJR) announced the development of a new product whose exterior resembles a cigarette but whose composition is based on a technology not previously associated with conventional cigarettes. The device contains an insulated carbon fuel element at one end that is ignited and emits heat that is drawn across a bead-filled aluminum chamber, around which tobacco is wrapped. The chamber contains nicotine from a tobacco extract, flavorings, and a humectant. These are nebulized to form a smoke-like aerosol containing nicotine, carbon monoxide, carbon dioxide, and other ingredients. The company claims that less sidestream smoke is released into the environment. RJR also claims that the new product results in a substantial reduction in the number and concentration of compounds delivered to the user (RJR 1985b, 1987, 1988). However, many of the toxic and carcinogenic constituents typically present in the "tar" component of tobacco smoke (e.g., benzo(a)pyrene) are still present in the aerosol (RJR 1988). In addition, concern has been expressed that the product can be manipulated easily to allow it to be used to deliver "crack" cocaine (Cone and Henningfield 1989).

In October 1988, R.J. Reynolds began test marketing this product under the name Premier. The FDA has been petitioned by the American Medical Association and the Coalition on Smoking OR Health to exert jurisdiction over the new product on the grounds that it is a drug or medical device and that health claims are being made (AMA 1988, Coalition on Smoking OR Health 1988b). As of November 1988, the FDA had both petitions under review. (See Chapter 5.)

Summary

Since the first Surgeon General's Report in 1964, a number of proposals have been made for FDA or other agencies to regulate tobacco products or their ingredients because of their effects on health and safety. These efforts have been unsuccessful except in a few cases when manufacturers made health claims or when FDA deemed the product to be a food. Since there are no known safe levels for tar, nicotine, or other tobacco ingredients, in the absence of legislation, FDA regulation would probably have resulted in a ban of tobacco products, even those that might have been made less hazardous than conventional cigarettes. Instead of allowing regulation by Federal agencies, Congress in most cases reserved to itself jurisdiction over tobacco products, banned tobacco advertising in broadcast media, and required a disclosure of risks on packages and print ads (See Part I of this Chapter). This approach, however, allowed tobacco manufacturers to modify products and introduce new ones without subjecting them to the scrutiny of Federal agencies concerned with health and product safety.

During the early 1970s, low-yield cigarettes were introduced and implicitly promoted as being less hazardous than conventional products (Davis 1987; US DHHS 1981a; Chapter 5). Beginning in the late 1970s smokeless tobacco was more aggressively marketed as an alternative to smoked tobacco. Sheppard (1985) has described this as the "controlled" tobacco product cycle in which cigarette manufacturers manage existing demand and create new demand by varying the form of the tobacco product as public awareness about the dangers of traditional cigarettes increases.

Several approaches have been proposed to increase the regulation of tobacco products without resulting in a total ban. The first proposal would regulate new products or new product modifications while exempting existing products from regulatory review. An international example of this approach to product regulation concerns the introduction of smokeless tobacco products into countries with no established smokeless tobacco users. In 1987, the World Health Organization Study Group on Smokeless Tobacco recommended that such countries prohibit smokeless tobacco products before their use became common (WHO, in press). Based on this recommendation, four nations whose residents have no history of using oral snuff (Australia, New Zealand, Hong Kong, and Saudi Arabia) banned the manufacture, sale, or importation of oral snuff; Ireland banned the sale of snuff, and Great Britain had legislation pending as of November 1988. A second approach to tobacco product regulation would continue to recognize the special status of tobacco products but regulate their marketing and sales in line with the marketing of other drugs and alcohol. A third approach is to use legislation to bring tobacco products under the jurisdiction of Federal regulatory agencies without banning them by explicitly limiting the power of the Federal agency. Legislation introduced in Congress in 1987 included provisions that would bring tobacco products under regulatory control of the FDA and the CPSC (H.R. 2376 and H.R. 3294), but these bills were not enacted.

CONCLUSIONS

Part I. Policies Pertaining to Information and Education

1. The Federal Government's efforts to reduce the health consequences of cigarette smoking have consisted primarily of providing the public with information and education about the hazards of tobacco use. Two of the most well-known mechanisms are the publication of Surgeon General's Reports and the requirement of warning labels on cigarette packages. A system of rotating health warning labels is now required for all cigarette and smokeless tobacco packaging and advertisements.
2. Current laws do not require health warning labels on all tobacco products and do not require monitoring of the communications effectiveness of the warnings. Furthermore, existing laws do not provide administrative mechanisms to update the contents of labels to prevent the overexposure of current messages or to reflect advances in scientific knowledge, such as new information about the addictive nature of tobacco use.
3. There is insufficient evidence to determine the independent effect of cigarette warning labels, particularly the rotating warning labels required since 1985, on public knowledge about the health effects of smoking or on smoking behavior.
4. Information about tar and nicotine yields appears on all cigarette advertisements but not on all cigarette packages. Levels of other hazardous constituents of tobacco smoke, such as carbon monoxide, hydrogen cyanide, and ammonia, are not disclosed on packages or advertisements. Little information is available to the public about the identity or health consequences of the additives in tobacco products.

5. Declines in adult per capita cigarette consumption have occurred in years of major dissemination of information on the health hazards of smoking. These include 1964, the year of the first Surgeon General's Report on smoking and health, and 1967–70, when antismoking public service announcements were widely broadcast on radio and television, as mandated by the Federal Communications Commission's Fairness Doctrine.
6. In 1985, when cigarette advertising and promotion totaled 2.5 billion dollars, cigarettes were the most heavily advertised product category in the outdoor media (e.g., billboards), second in magazines, and third in newspapers. Over the past decade, the majority of cigarette marketing expenditures has shifted from traditional print advertising to promotional activities (e.g., free samples, coupons, sponsorship of sporting events).
7. An estimated 1 percent of the budget allocated to disease prevention by the U.S. Department of Health and Human Services is devoted specifically to tobacco control. These expenditures totaled 39.5 million dollars in 1986.

Part II. Economic Incentives

1. Cigarette excise taxes are imposed by the Federal Government (16 cents per pack), all State governments, and nearly 400 cities and counties. On average, Federal and State excise taxes add 34 cents per pack to the price of cigarettes. Cigarette excise tax rates have fallen since 1964 in real terms because the rate and magnitude of periodic tax increases have not kept pace with inflation.
2. Studies demonstrate that increases in the price of cigarettes decrease smoking, particularly by adolescents. It has been estimated that an additional 100,000 or more persons will live to age 65 as a result of the price increases induced by the 1983 doubling of the Federal excise tax on cigarettes.
3. In 1964, smoking status was not considered in the determination of insurance premiums. Currently, nearly all life insurers but only a few health, disability, and property and casualty insurers offer premium discounts for nonsmokers. Few health insurers reimburse for the costs of smoking cessation programs or treatment.

Part III. Direct Restrictions on Smoking

1. Restrictions on smoking in public places and at work are growing in number and comprehensiveness, as a result of both Government actions and private initiatives. Forty-two States and more than 320 communities have passed laws restricting smoking in public, and an estimated one-half of large businesses have a smoking policy for their employees.
2. The goal of these smoking restrictions is to protect individuals from the consequences of involuntary tobacco smoke exposure, but they may also contribute to reductions in smoking prevalence by changing the attitudes and behavior of current and potential smokers. Insufficient research has been undertaken to determine the extent, if any, of these effects.

3. There are fewer legal restrictions on children's access to tobacco products now than in 1964, despite what has been learned since then about the dangers of tobacco use, its addictive nature, and the early age of initiation of smoking.
4. As of January 1, 1988, laws in 43 States and the District of Columbia restricted the sale of cigarettes to minors. Nevertheless, tobacco products are relatively easy for children to obtain through vending machines and over-the-counter purchases because of low levels of compliance with and enforcement of current laws.
5. Tobacco products have been exempted by law or administrative decision from the jurisdiction of Federal regulatory agencies under whose authority they might otherwise fall.

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